

## Remarks

Applicants wish to thank Examiners Aaron B. Colquitt and Charles Marmor, II for the interview kindly granted on March 3, 2008 in this case.

The first named inventor, Richard F. Kaplan, his undersigned counsel, Barry W. Sufrin, and Professor Richard R. Bootzin attended the interview. As noted in the interview, Dr. Bootzin is a Professor of Psychology and Psychiatry at the University of Arizona and directs the Insomnia Clinic of the University of Arizona Sleep Disorders Center. Dr. Bootzin is a pioneer in the behavioral treatment of insomnia and has been working in this field since at least 1972. Examiners Colquitt and Marmor were presented with Dr. Bootzin's current Curriculum Vitae at the interview.

As explained in the Background of the present application, insomnia is a complaint that sleep is difficult to initiate or maintain, or that it is not refreshing or restorative. People that suffer from insomnia have difficulty falling asleep or staying asleep, or wake too early. Insomnia is a widespread problem and the present invention offers unique solution to this problem.

As noted at the interview, the principal reference, U.S. Patent No. 5,928,133, is directed to an alarm clock for awakening a user at an optimal time within a preset time interval. Even assuming *arguendo* that the Halyak device will perform as taught, this reference does not address insomnia in any way. Most importantly, it does not include any means for processing information indicative of a subject's wake state or of a subject's sleep state as in the first element of independent claims 38 and 47 which were rejected under 35 U.S.C. § 102 as anticipated by Halyak. Also, this reference does not discuss or implement any behavioral therapy, as in the second element of independent claims 38 and 48. Furthermore, Halyak does not suggest any means for processing information indicative of a subject's wake state or of a subject's sleep state nor does it suggest the implementation of any behavioral therapy. It is therefore requested that the rejections of these two independent claims and their corresponding dependent claims over Halyak be withdrawn.

The objective of behavioral therapy is to alter behavior vis-à-vis insomnia. The user of the Halyak alarm clock, even if it works as promised, would not be expected to change his or her behavior as a result of using the device because there is no behavioral therapy component in this device or in its method of use. These distinctions of the present invention from Halyak are believed to be driven home by the amendments to claims 38 and 47. Amendments along these lines were proposed at the March 3, 2008 interview and received with an indication that, subject to further review of the language and of the teaching of Halyak, they appeared to distinguish the claimed invention over Halyak.

Dependent claims 39-41, 43 and 46, which were rejected as anticipated by Halyak, are directed to specific behavioral therapies (39), means for choosing behavioral therapies (40), passive wake/sleep determination means (41), supplemental use of active passive wake/sleep determination means (43), and optimizing the behavioral therapies for each subject based on wake/sleep information (46). These dependent claims are themselves neither anticipated nor obvious over Halyak because Halyak does not teach or suggest the use of behavioral therapies for any purpose (including treatment of insomnia) nor does it teach or suggest the use of any wake/sleep determination means.

Additionally, several of the remaining dependent claims rejected as anticipated by Halyak are directed to advanced features that are neither taught nor suggested by this reference. These include specific determination/alert regarding leaving the bed (48), means for processing data regarding completed sleep periods and upcoming sleep sessions (49), optimization of behavioral therapy for each subject (52), means for calculating time intervals corresponding to highest likelihood of being able to sleep (65), and the use of means for obtaining wake/sleep information prior to beginning treatment (67).

Claims 55-57 and 70 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Halyak in view of U.S. Patent No. 6,392,962 to Wyatt. Wyatt was also discussed at the interview.

Wyatt is directed to a wrist-mounted timer and an actuator in which contacts on a glove worn by the user will be separated at some point before or after the user falls asleep. The purpose of this device is to improve an insomniac's estimation of his or her total sleep time and sleep efficiency. Such a determination of sleep time and sleep efficiency requires the user to write down when he or she actually lays down and wakes up and to run a calculation in which the time to separation of the contacts is used in determining sleep time and sleep efficiency.

At the March 3, 2008 interview, Dr. Bootzin questioned whether this device actually indicates when the user falls asleep since the loss of motor control associated with the separation of the contacts is not a reliable indicator of the time that the user falls asleep. In view of this, users of the Wyatt device will calculate time to fall asleep and this may be at odds with their actual experience. For example, the Wyatt system might indicate to a user that it took only ten minutes to fall asleep because the contacts separated after ten minutes notwithstanding that it actually took the user, e.g., 30 minutes to fall asleep. The user may know or sense that it took a half hour to fall sleep. This inconsistency between the Wyatt time to fall asleep and the actual sensed time to fall asleep could upset an already concerned user leading to further bad sleep hygiene and continuing insomnia.

In rejecting claims 55-57 and 70 under 35 U.S.C. § 103, it was argued that Wyatt was capable of determining if the subject is in bed and displaying that data on a monitor or a printer. At the March 3, 2008 interview, however, the Examiners acknowledged that Wyatt does not teach or suggest either of these features. Therefore, subject to further post-interview review, the Examiners provisionally agreed that the rejection under 35 U.S.C. § 103 of claims 55-57 and 72 would be withdrawn. Accordingly, these dependent claims have been rewritten as new claims 73-76 to incorporate the independent claims on which they rely. Also, it is noted that the language of claims 48 and 55 has been clarified.

In view of the amendments to the claims, the discussion at the interview of March 3, 2008 and the arguments set forth above, the application is believed to be in good and proper form for allowance. Therefore, it is respectfully requested that this application be passed to issue. However, if in the opinion of the Examiners a telephone conference would expedite the prosecution of the subject application, Applicants request that the Examiners telephone the undersigned attorney at their convenience.

Respectfully submitted,

/barry w. sufrin/

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